K012210

AUG - 9 2001

Special 510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: July 13, 2001

2) Device name

Proprietary name: Accu-Chek™ Inform® Meter
Common name: whole blood glucose test system
Classification name: Glucose dehydrogenase, glucose

3) Predicate device

We claim substantial equivalence to the Roche Diagnostics Accu-Chek Advantage Meter.

Continued on next page

Special 510(k) Summary, Continued

4) Device Description

The Accu-Chek Inform system is addition to the Accu-Chek brand of blood glucose monitors that incorporates the fundamental scientific technology currently found in the Accu-Chek Advantage Meter.

The Accu-Chek Inform Meter is a modification to the Accu-Chek Advantage Meter that involves integrating the AccuData GTS unit's data gathering features into the meter. The modification does not affect the device's intended use. The Accu-Chek Inform Meter may be used in conjunction with the same test strips indicated for use with the Accu-Chek Advantage Meter, and the test principle described on the following page is not affected by the design modifications.

This modification can be accomplished due in part to the availability of palm-type computers (PDA). Our product designers modified the Accu-Chek Advantage Meter by building into its body an off-the-shelf PDA. The PDA module enabled our designers to integrate the AccuData GTS unit's data gathering features into the meter itself.

The Accu-Chek Inform Meter was designed to be convenient and easy to use.

5) Intended use

The Accu-Chek Inform Meter is designed to quantitatively measure the concentration of glucose in whole blood samples. The device is indicated for use by health care professionals and persons with diabetes mellitus.

Continued on next page

6) Comparison to predicate device

The Roche Diagnostics Accu-Chek Inform Meter is substantially equivalent to the Accu-Chek Advantage Meter, as the following table shows.

	Accu-Chek Advantage Meter (predicate device)	**Accu-Chek Inform Meter**
Intended use	The meter is designed to quantitatively measure the concentration of glucose in a whole blood sample.	No change
Indications for use	The device is indicated for professional use and over-the-counter sale.	No change
Fundamental scientific technology	The measurement is accomplished by applying a controlled voltage between two identical electrodes embedded within the test strip, which causes the reduced mediator formed during the glucose dehydrogenase reaction to be reconverted to an oxidized mediator. This generates a small current that is measured by the meter. The meter's software converts this electrical currency signal into a blood glucose value. The system's correlation to a comparative laboratory method is established by the manufacturer; each test strip vial is packaged with a calibration code key that the user insets into the meter to ensure an appropriate calibration.	No change
OTC User's Manual	Professional and lay person instructions included within one manual.	Professional and lay person instructions provided in separate manuals.
Analytical performance claims	Derived from testing with the two test strips listed above. Claims are stated in test strip package inserts. Meter model does not significantly affect analytical performance claims.	No change
Performance comparisons	Derived from testing with the two test strips listed above. Claims are stated in test strip package inserts. Meter model does not significantly affect method comparison results.	No change
Data management	Home use – blood glucose and liquid control testing results Health care provider (w/AccuData GTS) – blood glucose, liquid control, linearity, and proficiency testing results and operator and patient identification	No change
Technical Service	Accu-Chek Customer Care Center available to respond to customer questions via a toll-free telephone service around-the-clock, every day of the year.	No change

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 9 2001

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, IN 46250-0457

Re: 510(k) Number: K012210
Trade/Device Name: Accu-Chek™ Inform® Meter
Regulation Number: 862.1345
Regulatory Class: II.
Product Code: NBW, LFR
Dated: July 13, 2001
Received: July 16, 2001

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Special 510(k) Number (if known): K012210
Device Name: Accu-Chek™ Inform® Meter

Indications for Use:

The Accu-Chek Inform Meter is designed to quantitatively measure the concentration of glucose in whole blood samples. The device is indicated for use by health care professionals and persons with diabetes mellitus.

The Accu-Chek Inform Meter is an addition to the Accu-Chek brand of blood glucose monitors that incorporates the fundamental scientific technology currently found in the Accu-Chek Advantage Meter and Accu-Chek Complete Meter. The Accu-Chek Inform Meter is designed for use in conjunction with either the Accu-Chek Advantage or Accu-Chek Comfort Curve test strips.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kisha Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012210

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)